



To Whom It May Concern

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NanoCarrier Announces the Conclusion of NC-6004 Phase III Clinical Study for Pancreatic Cancer

NanoCarrier is pleased to announce that the Phase III clinical study for pancreatic cancer, one of the development programs of NC-6004 (Cisplatin Micelle), was concluded as the final report of the international clinical study was finalized. Detailed analysis of the study was conducted by Orient Europharma Co., Ltd. (OEP, Taiwan), the co-developer and licensee. We have been informed that OEP does not intend to disclose the details of the results.

NanoCarrier had been conducting a Phase III clinical study of the combination therapy with NC-6004 and Gemcitabine for pancreatic cancer since 2014. However, standard regimens in the treatment of pancreatic cancer have been recently changed, and Gemcitabine is not usually used for the 1st line treatment. Therefore, December 27, 2019, NanoCarrier announced with respect to the NC-6004 phase III study for pancreatic cancer that it has reached the conclusion that NDA will not be submitted with this study.

The domestic study results, which are part of the Phase III clinical study conducted by NanoCarrier, demonstrated the efficacy of NC-6004 in Japanese patients.

NC-6004+Gemcitabine Gemcitabine

Median OS 564 days (27 subjects) : 328 days (33 subjects) (p=0.0491)

Taking these results into consideration, NanoCarrier will advance the development of NC-6004, which takes advantage of the strengths of the formulation, by prioritizing the NC-6004 Phase IIb clinical study for head and neck cancer in combination with Keytruda. In the Phase IIb clinical study, NC-6004 is being developed as a value-added formulation with synergies in the efficacy of immune checkpoint inhibitors that have become mainstream in the current anticancer drug market.

This will have no impact on the business results for the fiscal year ending March 2021. NanoCarrier will proceed with activities for the practical application of NC-6004 and plans to conduct licensing activities in collaboration with OEP based on the results of clinical study.